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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,024	02/09/2005	Katsumi Ihara	2005-0097A	3975

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,024	IHARA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114 filed 06/05/09 and the Amendment and Response filed 04/13/09 and 04/17/09 is acknowledged.

Applicant has overcome the following rejection by virtue of the amendment to the claim: (1) The 35 U.S.C. §112, 2nd paragraph rejection of claim 6 has been withdrawn.

Claims 1-6 are pending in this action. Claims 1 and 6 have been amended. Claims 1-6 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05 June 2009 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO 01/87276) in view of Brantl et al. (US 4,826,686) and further in view of McQuinn (US 5,113,860).

With respect to claims 1 and 6, Kim et al. discloses a transmucosal patch containing fentanyl for transmucosal delivery, which comprises a drug layer containing fentanyl, an adhesive (maleic anhydride/vinyl ether copolymer) and thickener (hydroxyethyl cellulose) (pg. 10, lines 18-30). Kim teaches the use of hydrophilic polymer bases that affect the mechanical strength, elasticity and adhesiveness of the transdermal drug delivery system. Suitable hydrophilic bases taught include hydroxypropylmethyl cellulose, hydroxypropyl cellulose and hydroxyethyl cellulose (see page 9, lines 12-24). Kim teaches that the adhesiveness to the skin of the hydrophilic polymer base may be controlled through selection of the polymers. The adhesive property is maintained even under low pressure (p. 9, lines 25-31). Kim et al. further discloses in Fig. 1, an impenetrable support layer (1) on the drug layer, however fails to expressly disclose the inclusion of a backing layer. However, it is well known in the art to include a backing on a support layer, as taught by Brantl et al. (col. 4, lines 13-17). It

would have been obvious to one of ordinary skill in the art to include a backing layer in order to protect the patch from substantial disintegration over the time period which the patch is intended to remain adhered to the mucosal surface, as taught by McQuinn (col. 9, lines 5-12).

With respect to claim 4, the modified Kim et al. fails to expressly disclose the ratio of the adhesive and thickener being in the exact claimed range, however does disclose the adhesive being in the range of 0.1-15wt.% and the thickener being in the range of 0.1-20 wt.% (pg. 10, lines 20-23). Therefore, one of ordinary skill in the art could attain the ratio in the range of 5:95 to 97:3. It would have been obvious to one of ordinary skill in the art to modify the ratio of adhesive to thickener of the modified Kim in order to attain a patch with desired properties (pg. 10, lines 22-30). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, USPQ 233.

* * * * *

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Brantl et al. and further in view of McQuinn and further in view of Yamaguchi et al. (US 5,820,877).

With respect to claim 2, the modified Kim et al. addresses all the limitations of claim 1, however fails to expressly disclose the fentanyl salt is fentanyl citrate.

Yamaguchi et al. discloses a permucosal patch for delivering fentanyl citrate (col. 3, lines 59-60). It would have been obvious to one having ordinary skill in the art at the

time the invention was made to modify the fentanyl salt to be fentanyl citrate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

* * * * *

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Brantl et al. and further in view of McQuinn and further in view of Miller, II et al. (US 2004/0086551).

With respect to claim 3, the modified Kim et al. addresses all the limitations of claim 1, however fails to expressly disclose the drug release rate from the drug layer is 50% within one hour. Miller, II et al. teaches a fentanyl patch having a drug release rate of 50% within one hour, as illustrated in Figs. 4 and 5. It would have been obvious to one of ordinary skill in the art to modify the drug release rate, as desired, in order to provide an effective immediate release of drug from the patch.

* * * * *

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Brantl et al. and further in view of McQuinn and further in view of Yamaguchi et al. and further in view of Miller, II et al.

With respect to claim 5, the modified Kim et al. addresses all the limitations of claims 1 and 2, however fails to expressly disclose the drug release rate from the drug layer is 50% within one hour. Miller, II et al. teaches a fentanyl patch having a drug

release rate of 50% within one hour, as illustrated in Figs. 4 and 5. It would have been obvious to one of ordinary skill in the art to modify the drug release rate, as desired, in order to provide an effective immediate release of drug from the patch.

* * * * *

Response to Arguments

Applicant's arguments filed 13 April 2009 have been fully considered and were found to be partially persuasive.

- **Rejection under 35 U.S.C. §112, 2nd paragraph:**

Applicant argued, "Optionally has been changed to 'further', which is consistent with the 'consists of' language of claim 6. Applicant's arguments were persuasive based on the amendment to claim 6. Accordingly, the 35 U.S.C. §112, 2nd paragraph rejection of claim 6 has been withdrawn.

- **Rejection under 35 U.S.C. §103(a) over Kim (WO 01/87276), Brantl (US 4,826,686) and McQuinn (US 5,113,860):**

Applicant argued, "Kim et al. do not teach or suggest a patch comprising a support layer hardly soluble or insoluble in water comprising ethyl cellulose and hydroxypropyl cellulose, as recited in amended claim 1. Kim et al. merely disclose a usual backing layer. In Kim et al., the hydrogel composition contains a hydrophilic compound, a lipophilic compound and a compatibilizer selected from an acrylate polymer in order to compatibilize both compounds as essential ingredients, as well as an active drug. The drug layer of the present invention contains methyl vinyl ether-maleic anhydride copolymer as an adhesive agent, and HPC, HPMC or HEC as a thickener. A compatibilizer, such as an acrylate polymer, is not contained therein (claim 6), and does not need to be contained therein."

Applicant's arguments have been fully considered but were not found to be persuasive. It is noted that Kim teaches the use of hydrophilic polymer bases that affect the mechanical strength, elasticity and adhesiveness of the transdermal drug delivery system. Suitable hydrophilic bases taught include hydroxypropylmethyl cellulose, hydroxypropyl cellulose and hydroxyethyl cellulose (see page 9, lines 12-24). Kim teaches that the adhesiveness to the skin of the hydrophilic polymer base may be controlled through selection of the polymers. The adhesive property is maintained even under low pressure (p. 9, lines 25-31). Applicant's argument that "a compatibilizer, such as an acrylate polymer, is not contained therein or needed to be therein (claim 6)" was not persuasive since the instant claim language does not preclude the use of the acrylate polymer of Kim. Claim 6 is dependent upon claim 1, whereby claim 1 is open to the inclusion of additional agents or elements asides from those instantly recited and thus permits the acrylate polymer of Kim. Note in particular that claim 6 permits the presence of a "absorption promoting agent". Acrylates are polymers that are known to aid in absorption and thus fall within the "absorption promoting agent" category of claim 6. As a result, the acrylate polymer of Kim is permitted in the formulation of the instant invention and is not excluded therein, given the present claim language. For these reasons, Applicant's arguments were not persuasive.

Applicant argued regarding Brantl stating, "The support layer of Brandtl consists of a laminate of a thin aluminum foil and polyethylene film. Thus, the support layer is different than that of the present invention."

Applicant's arguments have been fully considered but were not found to be persuasive. The secondary reference is ample for all that it suggests and teaches to one of ordinary skill in the art. Namely, the secondary reference demonstrates that it is well known in the art to employ

a backing on a support layer. With regards to use of the components claimed (ethylcellulose, hydroxypropylmethyl cellulose), the primary reference of Kim initially teaches such components in their transdermal patch.

Applicant argued regarding McQuinn stating, "The reference is not analogous to the present invention."

This argument was not held to be convincing. McQuinn is directed to an analogous field of endeavor. McQuinn discloses a patch. The instant invention also claims a patch. Thus, it cannot be seen as to how McQuinn would be non-analogous art as both the present invention and the prior art are directed to devices in the form of a patch.

- **Rejection of claims 2, 3 and 5 over Kim, Brandtl, McQuinn and Yamaguchi (US 5,820,877):**

Applicant argued, "The arguments above with respect to Kim et al., Brantl et al. and McQuinn are equally applicable to these rejections. Yamaguchi et al. and Miller, II et al. do not cure the deficiencies identified above. Therefore, claim 1 would not have been obvious over the applied references."

Applicant's arguments were not deemed persuasive. The limitations of claims 2, 3 and 5 are met by the combination of reference teachings. The art in combination teaches the fentanyl citrate salt form (claim 2) and the particular release rate of claim 3 and 5 (50% within one hour). Applicant has not established any patentable distinction which would accrue over the prior art patch formulations. The art in combination is vividly suggestive of a patch as instantly claimed comprising the same structural features, ingredients and elements as that presently sought by Applicant. The rejections of record have been maintained.

Conclusion

- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

August 31, 2009